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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/725,374

12/03/2003

Ralph Schneider

31698-2130

3133

71040

7590

04/16/2008

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EXAMINER

CAMPBELL, VICTORIA P

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

04/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/725,374	Applicant(s) SCHNEIDER ET AL.	
	Examiner VICTORIA P. CAMPBELL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,7,9-12,15 and 22-34 is/are pending in the application.
- 4a) Of the above claim(s) 1,4,7,9-12,15,20-25,33 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/5/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 33 and 34 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: a catheter shaft wherein the bending section is formed as a soft-annealed section of the catheter which is then surrounded by a spring is not encompassed by the drawing or description set forth by the applicant relative to the elected Species A, shown in Figure 1.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 33 and 34 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

This is the second Office Action following the Request for Continued Examination based on the 10/725374 application filed December 3, 2003, which claims priority to EPO application 02027767.9, filed December 11, 2002. Claims 26-32 as amended are currently pending and considered below.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states,

"the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. Namely, the specification lists USPN 5,569,200.

Specification

3. The disclosure is objected to because of the following informalities:
- Paragraph [0003] line 2 states "above mentioned problems" however no drawbacks of existing catheter systems are mentioned.
- Paragraph [0006] line 1 reads "This object is achieved a catheter comprising a catheter shaft" which is awkward and should be rewritten.
- Paragraph [0007] lines 1-3 are a fragment, not a sentence, consider revising.
- Appropriate correction is required.

Claim Objections

4. Claim 26 recites the limitation "the second of the catheter shaft" in line 6 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 26-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 6,048,338 to Larson et al in view of USPN 5,800,451 to Buess et al.

Regarding the instant claims, Larson et al teach the following:

26. A catheter (Fig. 1, #20) comprising: a catheter shaft (Fig. 1, #22) having a distal end (Fig. 1, #42) and a proximal end (Fig. 1, #21), a balloon secured to the distal end (Fig. 1, #24); and a fitting secured to the proximal end (Fig. 1, #26), [...], wherein the bending section includes a spiral cut (Fig. 5, #126) formed in the

proximal end, and wherein a fluid impermeable covering is disposed to seal the spiral cut (Fig 5, #200).

28. The catheter of claim 26, wherein the fitting includes a passageway in flow communication with the catheter shaft (Fig. 1, #52).

30. The catheter of claim 26, wherein the fluid impermeable covering is shaped as a sleeve or tube (Fig. 5, #200).

32. The catheter of claim 26, wherein the fitting comprises a transition member connected to the proximal end, and wherein the transition member is structured to prevent unintended kinking of at least a portion of the bending section (Fig. 1, #23).

However, Larson et al fail to teach or disclose that the permanently affixed bending section of the catheter is at the proximal end. However, Buess et al teach:

26. wherein the proximal end includes a permanently affixed bending section (Fig. 1, #11) having a flexibility (Fig. 1, #23, #24) greater than that of the section of the catheter shaft joining the proximal end (Fig. 1, #17).

31. The catheter of claim 26, wherein the fluid impermeable covering (Fig. 1, #11) is adhesively bonded to the bending section (Col. 4, lines 60-64, examiner is interpreting adhesively in its broadest sense to mean permanently bonded).

Larson et al and Buess et al are analogous art because they are from the same field of endeavor/problem solving area of access tubing. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Larson et al and Buell et al before him or her to modify the catheter of Larson et al to

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include the proximal portion described by Buell et al because it permits flexibility at the proximal end without compromising the lumen of the device (Buell et al). Therefore, it would have been obvious to combine Larson et al with Buell et al to obtain the invention in the instant claims.

Regarding claims 27 and 29, Larson et al and Buell et al teach all of the limitations of claim 26 as shown above. However, they fail to teach or disclose the fitting being a luer fitting and that the spiral cut is formed with a selectable number of spiral sections. Regarding claim 27, using a luer fitting as opposed to the particular fitting shown by Larson et al would have been obvious to one having ordinary skill in the art as a luer fitting is just one of several commonly used fittings to join surgical tools. Regarding claim 29, the characteristic that the spiral cut is formed with a selectable number of sections is inherent to creating the spiral cut because by simply by making the cut, one is selecting a number of spiral sections. Additionally, no benefit is disclosed by the applicant for being able to select the number of sections, and therefore the examiner believes that any number of sections would accomplish the task at hand.

Response to Arguments

9. Applicant's arguments with respect to claims 1, 3, 4, 7, 9, 10, 17, 17, 19, and 20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763